

53. (New) The method of claim 50, wherein the cancer is a sarcoma, carcinoma, neuroblastoma, glioma or drug resistant cancer.

54. (New) A method of treating cancer in an animal in need of the treatment, comprising administering an anticancer effective amount of the composition of claim 49 to said animal.

55. (New) The method of claim 54, wherein said animal is a human.

56. (New) The method of claim 54, wherein the cancer is a brain cancer, breast cancer, lung cancer, ovarian cancer, colon cancer, stomach cancer or prostate cancer.

57. (New) The method of claim 54, wherein the cancer is a sarcoma, carcinoma, neuroblastoma, glioma or drug resistant cancer. --

REMARKS

Pursuant to 37 CFR 1.173(g), the amendments in this Response are made relative to the claims in the instant patent (US 5,681,589).

The amendment to claim 1 regarding R² is made to correct an error in the minimum number of carbon atoms that can be in the alkenyl or alkynyl group in the definition of R². Claim 1 in the instant patent recites that R² can be "an alkenyl or alkynyl group having from 1 to 23 carbon atoms in the aliphatic chain" (see column 25, lines 37-39). However,

to one skilled in the art, it was apparent that an alkenyl or alkynyl group cannot have only 1 carbon atom because there must be at least $C=C$ or $C\equiv C$ in the alkenyl or alkynyl group, respectively. The amendment to claim 1 related to R^2 is aimed at correcting this error by making the minimum number of carbon atoms to be 2 in the alkenyl or alkynyl group for R^2 . Applicants submit that this amendment would not narrow the scope of the amended claim limitation because, to a person of ordinary skill in the art, the scope of "an alkenyl or alkynyl group having from 2 to 23 carbon atoms in the aliphatic chain" is not narrower than "an alkenyl or alkynyl group having from 1 to 23 carbon atoms in the aliphatic chain" based on the person's understanding of organic chemistry.

The insertion of "component" at the end of claim 1 is aimed at making it more clear that "the lipid" refers to "a lipid component" in line 1 of claim 1. This amendment also would not narrow the scope of the amended claim limitation because, to a person skilled in the art, it was apparent that "the lipid" in claim 1 of the instant patent means the "lipid component" recited in line 1, since the "lipid component" is that only time that the word "lipid" has been used before the recitation of "the lipid" at the end of claim 1.

The amendment to X^1 made in Claim 1 (Amended Twice) is done to more properly present the amendment with deletions enclosed with square brackets and insertions underlined as required by 37 CFR 1.173. However, the definition of X^1 in Claim 1 (Amended Twice) is the same as that in Claim 1 (Amended) presented in the Amendment filed on July 25, 2000.

Similar to claim 1, the error concerning the minimum number of carbon atoms in the alkenyl group or alkynyl group in the definition of R² in claim 16 is corrected by the above amendment to claim 16.

In both claims 1 and 16, the replacements of "carbons" with "carbon atoms", "a fluorine" with "a fluorine atom" and "a chlorine" with "a chlorine atom" are made to be more grammatically correct. Applicants submit that the replacements would not narrow the scope of the amended claim limitations.

The new claims 33-57 added are supported by the specification at column 3, lines 28-46, column 4, lines 11-40, column 15, line 38, column 16, line 26 and column 18, lines 21-51.

With the addition of claims 33-57, claims 1-57 are pending. To help Examiner Kishore follow the amendment more easily, the sources of all the claims are shown below.

| <u>Claim Number</u> | <u>Source</u> |
|---------------------|---------------------------------|
| 1-15 | Patented claims in US 5,681,589 |
| 16-32 | Added before this amendment |
| 33-57 | Added with this amendment |

In addition, to make it easier for the examination on the merits, the subject matters of claims 1-57 are listed in the table below.

| <u>Claim Number</u> | <u>Claimed Subject Matter</u> |
|---------------------|---|
| 1-12, 32, 34-48 | Liposome |
| 16-30 | Compound |
| 13, 31, 33, 49 | Composition comprising the liposome or compound |
| 14, 15, 50-57 | Methods of using the composition |

Information Disclosure Statement

As requested by the Examiner, a PTO-1449 is attached citing US 5,415,855. The publication year, volume number and page numbers of the article by S. Martin previously cited in an early IDS is also provided in the PTO-1449 attached (the article was published in 1993 in volume 3, pages 141-144, of Cell Biology Trends).

Claim Rejection — 35 U.S.C. 251

Claims 16-32 were rejected as being an **improper recapture** of broadened claimed subject matter. Applicants respectfully traverse the rejection.

The Office Action states that a broadening aspect is present in the reissue application which was not present in the application for patent and the broadening aspect in the reissue application relates to subject matter that applicant previously patented prior to the prosecution of the application. The Office Action then concluded that "the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251".

Applicants respectfully disagree. According to the case law (*Hester Industries v. Stein*, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 45 USPQ2d 1161 (Fed. Cir.

1997); *Ball Corp. v. United States*, 221 USPQ 289 (Fed. Cir. 1984)) relied upon by the Examiner, the recapture rule bars the allowance of a reissue claim that is broader than an original claim surrendered during prosecution of the patented application **in an effort to overcome a prior art rejection**. See *Hester Industries*, 45 USPQ2d at 1648; *In re Clement*, 45 USPQ2d at 1164.

The instant reissue application is for the reissue of U.S. Patent 5,681,589 (the '589 Patent) issued from Application No. 08/545,164 (Application '164). In the instant reissue application, claims 16-30 are drawn to a compound. During the prosecution of Application '164, no compound claims were cancelled or narrowed via an amendment after the Preliminary Amendment was filed on October 19, 1995, let alone cancelled or narrowed **in order to overcome a prior art rejection**. Thus, the recapture rule should not apply in the instant reissue application for claims 16-30. Withdrawal of the rejection of claims 16-30 under 35 U.S.C. 251 is requested because claims 16-30 does not constitute a recapture of the subject matter of compound claims surrendered during the prosecution of Application '164 in order to overcome a prior art rejection.

Despite the Office Action's allegation that claim 31 was drawn to a compound, claim 31 is actually drawn to a pharmaceutical composition. Claim 13 of the '589 Patent was also drawn to a pharmaceutical composition and claim 13 was issued from claim 87 of Application '164. Claim 87 of Application '164 was narrowed once during the prosecution of Application '164, but not as an attempt to overcome any prior art rejection. Since claim 31 does not claim subject matter similar to or broader than the subject matter of claim 87 of Application '164 surrendered during prosecution for any purpose, let alone for the purpose

of trying to overcome any prior art rejection, the recapture rule also should not apply to claim 31. The addition of claim 13 does not constitute any recapture of subject matter surrendered during the prosecution of Application '164 for the purpose of overcoming any prior art rejection.

Similarly, the Office Action erroneously asserted that claim 32 was drawn to a compound. However, claim 32 is actually drawn to a method. Claim 14 of the '589 Patent was also drawn to a method and claim 14 of the '589 Patent was issued from claim 88 of Application '164. Claim 88 was amended once during the prosecution of Application '164, but not for the reason of trying to overcome any prior art rejection. Since claim 32 does not claim subject matter similar to or broader than the subject matter of claim 88 of Application '164 surrendered during prosecution for any purpose, let alone for the purpose of trying to overcome any prior art rejection, the recapture rule also should not apply to claim 32.

As a result, withdrawal of the rejection of claims 31 and 32 under 35 U.S.C. 251 is also requested.

Application '164 was a divisional application of Application No. 08/383,291 (the parent application) which issued as U.S. Patent 5,631,394 (the parent patent). The Office Action appeared to reject, as improper recapture, claims 16-32 as claims of similar or broadened scope to those issued in the parent patent more than two years prior to the filing of the instant reissue application. However, none of the recapture-rule case law relied upon by the Examiner mentions the recapture rule being triggered by a time limit of "more than two years prior to the filing of this reissue application" as alleged by the Office Action.

For instance, in *In re Clement* and *Ball Corporation*, the reissue applications were both filed within two years of the issue dates of the patents for which reissues were sought (see *Clement*, 45 USPQ2d at 1161; *Ball Corporation*, 221 USPQ at 292). In *Hester Industries*, the first reissue application was filed on the two-year anniversary of the issue date of the patent for which the reissue was sought (46 USPQ2d at 1644). Since the recapture rule is not related to whether a reissue application was filed more than 2 years after the issue date of a patent, Applicants submit that the rationale for the Office Action's rejection based on the recapture rule is misplaced. This is another reason why the rejection under 35 U.S.C. 251 should be withdrawn.

The Office Action asserted that the claims drawn to a liposome as originally filed in the parent application were not elected in response to a restriction requirement in the parent application. However, applicants do not understand the relevance of this assertion of the Office Action. Even though applicants did not elect claims drawn to the liposome in the parent application, the claims drawn to the liposome were cancelled in the parent application as a result of the restriction requirement, not as a result of an attempt to overcome any prior art rejection. Additionally, claims drawn to a liposome were rightfully prosecuted in a divisional application (Application '164). Applicants filed the instant reissue application seeking the reissue of the '589 Patent within two years of the issue date of the '589 Patent (issued from Application '164) with claims 16-32, wherein claims 16-30 were drawn to the compound. In other words, claims 16-30 were on file within 2 years of the issue date of the '589 Patent. Thus, applicants submit that claims 16-32 meet the requirements of 35 U.S.C. 251 which permits a reissue patent to be granted enlarging the

scope of the claims of the original patent as long as the claims with the enlarged scope are filed within two years from the grant of the original patent. See *In re Graff*, 42 USPQ2d 1471 (Fed. Cir. 1997); *In re Doll*, 164 USPQ 218 (CCPA 1970). The instant reissue application is seeking a reissue of the '589 Patent which is "the original patent" under 35 U.S.C. 251. The reissue application is not seeking a reissue of the parent patent.

Withdrawal of the rejection under 35 U.S.C. 251 is requested.

Objection

Claim 1 was objected to regarding the manner line 11 was amended. However, applicants found no amendment in line 11 of Claim 1 (Amended). Applicants assume that the objection was directed toward the amendment to the definition of X¹. Applicants have presented the amendment of X¹ again in accordance with the requirements of 37 CFR 1.173. Withdrawal of the objection is requested.

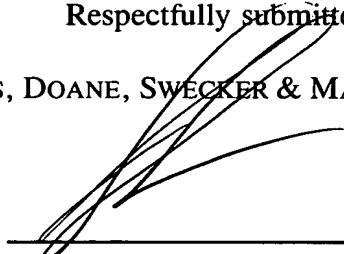
Conclusion

With the above reasoning, applicants respectfully submit that the reissue application is in a condition for allowance.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By:



Teresa Stanek Rea
Registration No. 30,427

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: August 20, 2001